UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
Houston Division

ELAINE GEORGE, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION and GUIDANT CORPORATION, Defendants.	)	Civil Action No. 4:07-cv-2467 Jury Trial Demanded

SECOND AMENDED COMPLAINT

Plaintiff Elaine George files this Second Amended Complaint against Boston Scientific Corporation and Guidant Corporation (collectively, "BSC" or "Defendants") and alleges as follows:

Case History

1. On or about November 9, 2006, Ms. George filed this action using her maiden name, Elaine Bennett, under seal in the Northern District of Illinois. She filed her First Amended Complaint on or about March 27, 2007. The action alleged primarily that Defendants violated the False Claims Act, 31 U.S.C. §3729 et seq., and defrauded the United States by causing the submission of false or fraudulent Medicare claims for procedures performed using Defendants' cardiac ablation products. Ms. George also sought damages arising from defendants' violation of the anti-retaliation provisions of the False Claims Act, 31 U.S.C. § 3730(h) and the public policy of the State of Illinois.

2. The case was transferred to the Southern District of Texas during the last quarter of 2006. On August 21, 2009, the government notified the Court that it was declining to intervene in the *qui tam* case. On March 31, 2011, the Court granted the Defendants' motion to dismiss, holding

primarily that the allegations were not detailed enough to comply with the technical pleading requirements of Federal Rule of Civil Procedure 9(b). The Court permitted Plaintiff time to amend her complaint. Ms. George now files this amended pleading addressing only her claims relating to her retaliatory discharge.

3. Ms. George's suit seeks damages against Defendants for their termination of her employment in retaliation for her efforts to challenge defendants' illegal, off-label marketing of their cardiac ablation devices.

Parties

4. Elaine George is a resident of Saint Louis County, Missouri. Ms. George was hired by Defendants on June 12, 2006 to work as a territory manager in the Cardiac Surgery Division of its Midwest region. Ms. George worked for Defendants in Central Illinois and throughout the state of Missouri until she was terminated on September 28, 2006.

5. Defendant Boston Scientific Corporation is headquartered in Natick, Massachusetts. Boston Scientific develops, manufactures and markets medical devices. On April 21, 2006, Boston Scientific acquired defendant Guidant Corporation, subsuming Guidant's Cardiac Rhythm Management and Cardiac Surgery divisions. In her earlier complaints, Ms. George alleged that Boston Scientific violated the False Claims Act by causing the submission of fraudulent Medicare claims for the off-label use of its microwave surgical ablation system to treat atrial fibrillation. Boston Scientific's Cardiac Surgery Division, which employed Ms. George, was acquired by Maquet in 2008.

6. Defendant Guidant Corporation was headquartered in Indianapolis, Indiana. Guidant designed, developed and marketed cardiovascular medical products, including the Flex 4, 10, and FlexView Microwave Surgical Ablation System. On April 21, 2006, Guidant's Cardiac Rhythm

Management and Cardiac Surgery units became part of Boston Scientific, and Guidant's vascular and endovascular businesses became part of Abbott Vascular. Prior to that time, Guidant violated the False Claims Act by causing the submission of fraudulent Medicare claims for the off-label use of its microwave surgical ablation system to treat atrial fibrillation.

7. Ms. George was hired to work in the Cardiac Surgery Division at a time of transition from Defendant Guidant to Defendant Boston Scientific. She was hired by Guidant personnel and underwent three days of training with Guidant's Human Resources personnel at Guidant's Indianapolis, Indiana facility. She participated in Initial Training School at Boston Scientific's facility in Santa Clara, California. For purposes of this action, Defendant Guidant and Defendant Boston Scientific are substantively one and the same.

Jurisdiction and Venue

8. This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. §1331 and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730.

9. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the Defendants have at least minimum contacts with the United States. Moreover, the Defendants can be found in and transact, or have transacted, business in the Southern District of Texas.

10. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because the Defendants can be found in and transact, or have transacted, business in the Southern District of Texas.

Background Allegations

11. Ms. George's retaliatory discharge occurred because she accused her employer of defrauding the United States through the Medicare program in violation of the False Claims Act.

The Medicare Program

12. Medicare is a federally funded health insurance program primarily benefitting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. Medicare, the nation's largest health insurance program, provides health insurance to people age 65 and over, those who have end-stage kidney failure, and certain people with disabilities.

13. The Centers for Medicare and Medicaid Services (CMS), a federal government agency, oversees the administration of Medicare but much of the daily operation of the Medicare program is managed through contracts with private insurance companies called Fiscal Intermediaries (responsible primarily for Medicare Part A claims) and Medicare Carriers (responsible primarily for Medicare Part B claims).

14. Medicare pays hospitals different amounts for various services based, in part, on the setting (*e.g.*, inpatient or outpatient) where the services were performed. In most cases, the procedure billed by the hospital is the most significant, if not the determinative, factor affecting the amount paid by Medicare to the hospital.

15. Physician services provided in conjunction with a procedure performed at a hospital (on either an inpatient or outpatient basis) are billed and reimbursed separately. Like hospital reimbursement, Medicare bases physician payment on the assumption that similar types of procedures consume a similar amount of resources, and thus deserve similar payment. Accordingly, Medicare pays physicians based on standardized procedure codes.

16. Federal law prohibits health care providers from making "any false statement or

representation of a material fact in any application for any . . . payment under a Federal health care program." See 42 U.S.C. § 1320-a-7b(a)(1). Similarly, Federal law requires providers who discover material omissions or errors in claims submitted to the Medicare to disclose those omissions or errors to the Government. See 42 U.S.C. § 1320-a-7b(a)(3). The requirement that providers be truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program. *See, e.g.,* 42 C.F.R. §§ 1003.105, 1003.102(a)(1)-(2).

17. Healthcare providers are also prohibited from violating the federal health care Anti-Kickback statute, 42 U.S.C. §1320a-7b(b). The Anti-Kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, medical device companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend products or procedures that may be paid for by a federal health care program.

Treatment of Atrial Fibrillation

18. Ms. George was hired to promote and sell Defendants' cardiac ablation medical device that was used solely to treat atrial fibrillation. Atrial fibrillation is a very fast and irregular beating of the heart, specifically the atria. It is the most prevalent type of arrhythmia leading to hospital admission. Over 2.2 million Americans suffer from atrial fibrillation, and approximately 160,000 new cases are diagnosed every year.

19. Physicians treat atrial fibrillation in a variety of ways. Treatment with antiarrhythmic drugs and anticoagulation is considered first-line therapy and standard of care. If drug therapy is unsuccessful, there are a variety of surgical procedures available to a patient. The cardiac "maze"

procedure is a form of open-heart surgery used to treat atrial fibrillation with strategic placement of incisions in both atria. By placing incisions along the surface of the heart, the surgeon attempts to disrupt the electrical impulses that are causing the patient's irregular heartbeat. The maze operation has not been widely adopted because of the need for cardiopulmonary bypass, the morbidity and complication rates, and because it is a difficult and very challenging procedure for the surgeon to perform.

20. In recent years, physicians have begun to try to treat atrial fibrillation by ablating — *i.e.,* removing or destroying — certain heart tissue with various forms of energy (*e.g.*, radio frequency, microwave) in order to disrupt the irregular electrical impulses that cause atrial fibrillation. In general, physicians have experimented with two types of ablation procedures: (1) catheter ablation and (2) surgical ablation.

21. Catheter ablation is a minimally invasive procedure that involves the use of a catheter that is threaded through the femoral artery in the patient's leg and into the heart. The catheter is equipped with a device that delivers radio frequency waves to the arrhythmia source. Catheter ablation is an outpatient procedure, performed by a specialized cardiologist, known as an electrophysiologist ("EP") in a catheterization lab. During a catheter ablation procedure, the patient is under conscious sedation (so the procedure uses less anesthesia), experiences fewer side effects, and typically will go home the same day. Catheter ablation has gained recognition as an effective procedure to treat atrial fibrillation. A large number of studies have reported high rates of successful treatment and a low incidence of complications with the catheter ablation techniques. In 2006, the American College of Cardiology, the American Heart Association Task Force on Practice Guidelines, and the European Society of Cardiology Committee for Practice all adopted "standards of care" and treatment protocols that include catheter-based ablation as a third-tier treatment option,

following drug therapy and cardioversion (a form of electrical shock therapy).

22. Surgical ablation is a surgical procedure performed in the operating room with the patient under general anesthesia. The procedure is a derivative of the maze procedure using microwave (or other) energy to create lesions on the surface of the heart to disrupt irregular electrical impulses. Surgical ablation procedures are generally performed by cardio-thoracic surgeons. Unlike catheter ablation procedures, which are performed on an outpatient basis, surgical ablation procedures are generally performed on an inpatient basis, requiring the patient to stay overnight in the hospital. Surgical ablation may be performed as either an open-heart procedure (often in conjunction with another open-heart procedure) or as a "minimally invasive" procedure. Because the efficacy and safety of surgical ablation is still under investigation, the procedure is considered more experimental and is less accepted than either catheter ablation or the maze surgical procedure.

Specific Allegations

23. In her dismissed *qui tam* case, Ms. George alleged that Defendants aggressively and illegally marketed their surgical ablation products to induce hospitals and physicians to purchase and use them specifically and exclusively for the non-FDA approved — *e.g.,* "off-label" — treatment of atrial fibrillation.

24. On multiple occasions, the FDA has denied specific approval for the use of surgical ablation systems to treat atrial fibrillation. Despite the fact that Defendants have not received FDA clearance supporting the specific use of their surgical ablation system to treat atrial fibrillation, Defendants trained their sales staff to promote their surgical ablation system exclusively for the off-label treatment of atrial fibrillation.

25. Ms. George further alleged that Defendants provided free training to doctors who

were willing to use their products and violated the Anti-Kickback Statute by providing kickbacks, such as free products, free advertising, and referrals, to hospitals and physicians who responded positively to Defendants' off-label promotional efforts. Ms. George alleges that because of her efforts to challenge Defendants' marketing and promotion practices, she was harassed and terminated from her job.

26. Ms. George was highly qualified for the position to which Defendants hired her. Her resume includes 16+ years of experience in the medical device industry and a proven history of success, as illustrated by past recognitions as a distinguished sales representative, recipient of President's Club awards and position as a top ten percent sales producer.

27. When she was hired, Ms. George received extensive instructions regarding her responsibility to train doctors to use Defendants' product off-label to treat atrial fibrillation, including a ten-day "Initial Training School"or "ITS" that focused on using the FLEX Microwave Ablation System. Prior to finishing the training, Ms. George was required to demonstrate to corporate trainers at Boston Scientific that she could "teach" proper lesion sets and surgical technique using Defendants' product to treat atrial fibrillation. Ms. George and all other sales representatives were required to accompany surgeons into the operating room to provide surgeons with detailed instructions regarding how they could use Defendants' product off-label to treat Medicare patients with atrial fibrillation.

28. It was during ITS, held from July 16-24, 2006 in Santa Clara, California, that Ms. George first was subjected to harassment for challenging the legality of Defendants' marketing activities involving the FlexView Surgical Ablation System.

29. One day of ITS instruction focused on the regulatory aspects of Defendants' business and included discussions regarding restrictions on off-label promotion and sales activities.

Defendants' compliance personnel discussed the dangers to the company associated with illegal off-label marketing. They described federal enforcement actions by the FDA and Department of Justice taken against competitors who had run afoul of the off-label marketing prohibition. They described how the government considered off-label marketing to be fraud and how other companies had incurred liability in the tens of millions of dollars as a result of their off-label marketing efforts. These presentations made it clear that off-label marketing was a type of fraud against the federal government that should be avoided at all costs.

30. As a result, Ms. George was very surprised when BSC's Charlie Merchant , a Sales Trainer, gave a presentation regarding restrictions on off-label marketing that made it appear to Ms. George that there was no legal way for BSC's cardiac ablation products to be promoted for the treatment of atrial fibrillation, a clearly off-label use. During the presentation, Ms. George asked for clarification as to whether there was any use for which BSC's surgical ablation products could be promoted legally. As soon as she asked her question, Mr. Merchant took a ten-minute break and proceeded to have a one-on-one discussion with Ms. George. During that time, Mr. Merchant reprimanded Ms. George and warned that such questions could jeopardize her employment status. She was told to stop asking questions regarding off-label marketing BSC's surgical ablation product line.

31. The following month, Ms. George attended BSC's National Sales Meeting from August 5-8, 2006 in Beaver Creek, Colorado where the company officially launched its new minimally-invasive Flex View Surgical Ablation System. During one session, the Flex View Product Manager revealed that BSC was close to obtaining FDA approval to use the device for the treatment of atrial fibrillation and that the company was in a "race" against its competitors to obtain such approval. During the session, Ms. George asked questions about the expected timing of the

FDA approval and whether, prior to FDA approval, BSC's promotion of the ablation system would be viewed by the government as an illegal and prohibited off-label promotional activity.

32. During a break in the session, Ms. George's manager, Meg Zavich, approached her in the restroom and reprimanded Ms. George for challenging BSC's marketing activities and for inquiring about prohibited off-label efforts. Ms. Zavich told her that if she harbored such concerns, she "might not be cut out for the job." Ms. Zavich said she might have made a mistake in hiring Ms. George and suggested that Ms. George consider resigning her position.

33. During the ensuing weeks, Ms. Zavich's unfounded criticisms of Ms. George increased exponentially. Ms. George complained to Ms. Zavich that she was not being held to the same standards or asked to perform the same functions as other new hires. She complained that the disparate treatment resulted from her challenging the company's off-label promotional activities.

34. Ms. Zavich did not deny any of this. She told Ms. George that it was her prerogative to hold Ms. George to different and higher standards and give her whatever assignments she wanted. Ms. Zavich repeated her suggestion that Ms. George consider resigning from the company.

35. At the end of August 2006, even though Ms. George had yet to complete her training, Ms. Zavich placed Ms. George on a Performance Improvement Plan ("PIP"), allegedly for poor performance. Ms. George objected to the PIP because it set primarily subjective goals, preventing her performance from being measured in any objective manner.

36. After the PIP was in place, harassment against Ms. George intensified. Ms. Zavich unreasonably required Ms. George, under threat of immediate termination for noncompliance, to reply within 30 minutes to every phone call or page from any account or BSC employee. Ms. Zavich then began calling Ms. George several times per week, including twice during the middle of the night between 2 a.m. and 5 a.m. Ms. Zavich explained the calls by simply saying that she was

an insomniac and could get much work done during the nighttime hours. The calls continued until Ms. George was terminated.

37. After the PIP was implemented, Ms. George contacted BSC's Human Resources Department for advice. She related to an HR representative, whose first name sounded like "Camaya," how she had been harassed since the training meetings and that she was being singled out for challenging the legality of BSC's off-label marketing practices for its surgical ablation products. Pursuant to the provisions of the BSC employee manual, Ms. George asked HR to intervene on her behalf to assist with the conflict that she and Ms. Zavich were experiencing. HR refused. Instead, she was told that if she discussed the matter with anyone inside or outside the company, she would be dismissed immediately. The HR representative suggested that Ms. George consider leaving the company.

38. Two senior sales representatives, Ted Permouth and Mike Quinn, told Ms. George that BSC was making her an example for the rest of the company. They warned her that management was out to get her.

39. During this time, small issues were distorted and used to trump up charges against Ms. George. For instance:

a. At the direction of acting manager Mike Quinn, who covered for Ms. Zavich during her vacation, Ms. George — as well as other reps in her region — waited to complete a report until Ms. Zavich returned so that Ms. Zavich could provide guidance as to the report's contents. Ms. George did so and — unlike the other reps — was criticized officially for not completing it earlier.

b. During the evening of Thursday, September 14, 2006, Ms. George attended in St. Louis, Missouri, a company promotional program directed to a group of cardiothoracic surgeons. During the dinner, she learned that an account, Lake Regional Hospital in Lake Ozark,

Missouri, required her services to train a Physician Assistant, Lu Ying-Yang, in the endoscopic vessel harvesting procedure that needed to be performed the following morning in connection with an open heart surgical ablation procedure. Ms. George drove to Lake Ozark, arriving at 3:15 a.m. on Friday, September 15. She began training Ms. Ying-Yang at approximately 4:30 a.m. and remained at Lake Regional throughout the entire case until 5 p.m. She arrived home at approximately 8:30 p.m. Ms. George was assured by Ms. Zavich, with whom Ms. George had remained in contact throughout the day, that Ms. George could turn in her weekly report (normally due by 5 p.m. on Friday) on Monday. Even though she woke up the following morning with strep throat, Ms. George submitted her report to Ms. Zavich by 1 p.m. on Saturday. Nevertheless, despite the explicit permission she received from Ms. Zavich to complete her report late, the untimely report was one of the reasons given for Ms. George's termination.

c. An incident involving Ms. George's efforts to return "trunk stock" to Charlie Merchant was used as a reason for Ms. George's termination, even though Mr. Merchant's version of events was not supported by available documents.

40. On September 25, 2006, Ms. George was given an ultimatum: resign or be fired. That same day, Mr. Merchant, who was conducting an "Initial Training School" session in Santa Clara, California, informed his class about Ms. George's termination, saying that it should serve as a lesson to keep your mouth shut and do your job. Three days later, on September 28, Ms. George received an email terminating her BSC employment.

41. Ms. George is not the only employee treated in a retaliatory manner by Ms. Zavich. At least two other employees, Scott Drikakis and Louann Brusa, both of whom challenged BSC's off-label marketing activities, were terminated or nearly terminated by Ms. Zavich. Ms. Zavich's allegations of poor performance against Ms. George, Mr. Drikakis, and Ms. Brusa (and likely other

employees) were pretexts for silencing troublemakers.

42. Since leaving BSC, Ms. George has had difficulty finding work. She initially took another sales position at a substantial pay cut while continuing to search for more suitable work. She was told by a recruiter that executives at BSC said that she was being blacklisted. Through recruiters or on her own, Ms. George diligently applied for work at nearly 40 companies affiliated with the medical device or healthcare industries.

43. Ms. George joined BSC with promises of high earnings. The company shared compensation examples showing an average territory manager earning in excess of $180,000 annually. Ms. Zavich told Ms. George that she would earn at least $250,000 during her first year on the job, based on salary, existing base business, and forecasted growth. To support her claims, Ms. Zavich showed Ms. George a territory analysis covering the preceding three years that included actual sales, bonus and commission figures.

COUNT I
False Claims Act
Retaliatory Discharge
31 U.S.C. § 3730(h)

44. Plaintiff realleges and incorporates by reference the allegations in the preceding paragraphs.

45. Pursuant to 31 U.S.C. § 3730(h), the False Claims Act prohibits an employer from discharging, demoting, suspending, threatening, harassing, or in any other manner discriminating against an employee in the terms and conditions of employment because of lawful acts done by the employee in furtherance of an action under the Act.

46. Ms. George engaged in activities protected by the False Claims Act by repeatedly challenging Defendants illegal off-label promotion of the Flex View Surgical Cardiac Ablation

system. By openly confronting Defendants about their illegal practices, Ms. George engaged in lawful, protected conduct taken "in furtherance of" a False Claims Act action.

47. Defendants' are sophisticated health care companies that understand that the failure to comply with prohibitions against off-label marketing can lead to false claims being submitted to Medicare and liability under federal laws, including the False Claims Act. Ms. George's protected conduct put Defendants on notice that they were committing fraud and of the distinct possibility of a *qui tam* action.

48. Defendants discriminated against Ms. George in the terms and conditions of her employment by harassing her, threatening her, and discharging her because she challenged Defendants illegal off-label promotion of the Flex View Surgical Cardiac Ablation system.

WHEREFORE, Ms. George requests that the Court enter judgment in her favor and against Defendants, awarding Ms. George:

a. two times the amount of back pay Ms. George would have earned but for Defendants' retaliatory conduct,

b. "front pay" in lieu of reinstatement with the same seniority status that she would have had but for the Defendants' discrimination;

c. interest on the back pay and front pay,

d. compensation for any special damages sustained as a result of defendants' discrimination,

e. all costs of this action, including attorneys' fees and expenses;

f. all relief necessary to make Ms. George whole; and

g. all such other and further relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury.

Respectfully submitted,

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